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(21) International Application Number: PCT/DK99/00593 (22) International Filing Date: 2 November 1999 (02.11.99) (30) Priority Data: PA 1998 01423 4 November 1998 (04.11.98) DK (71) Applicant (for all designated States except US): COLOPLAST A/S [DK/DK]; Høltedam 1, DK-3050 Humlebaek (DK). (72) Inventor; and (75) Inventor/Applicant (for US only): OTTO, Jens, Landkilde [DK/DK]; Frederiksborgvej 16A, 4.th., DK-2400 København NV (DK). (74) Common Representative: COLOPLAST A/S; Patent Dept., Nilausen, Kim, Høltedam 1, DK-3050 Humlebaek (DK).		(81) Designated States: AE, AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: CUTTING GUIDE FOR OSTOMY APPLIANCES (57) Abstract A method for making a customised ostomy appliance including an adhesive wafer comprising the steps: measuring the outer periphery of the stoma of the patient, recording the information relating to the measurements of the stoma area, transforming the recorded information into electronic form, utilising the electronic information to select physical attributes of the ostomy device and have physical attributes selected in accordance with the measurement information transferred to the ostomy appliance, in which method the information is utilised for printing a cutting guide pattern on a material for adhering to the adhesive wafer offers a simple and efficient method of customising ostomy appliances.		

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TITLE

Cutting Guide for Ostomy Appliances

Field of the invention

The present invention relates to a method for making a customised ostomy

- 5 devices of the type including a waste collection pouch adapted to be adhesively affixed to the skin surrounding the stoma and more particularly to cutting guides for ostomy devices customised to the stomal periphery of the user and a method for fabricating such cutting guides.

Description of the related Art

- 10 In connection with surgery for a number of diseases in the gastro-intestinal tract a consequence is, in many cases, that the colon, the ileum or the urethra has been exposed surgically and the patient is left with an abdominal stoma and the effluents or waste products of the body, which are conveyed through these organs, are discharged through the artificial orifice or opening and are collected
- 15 in a collection bag, which is usually adhered to the skin by means of an adhesive wafer or plate having an inlet opening for accommodating the stoma. Also in connection with a fistula, the patient will have to rely on an appliance to collect the bodily material emerging from such opening.

- Ostomy appliances are well known. Such appliances may be two-piece or
- 20 one-piece appliances. In both types of appliances, a body side member is attached to the wearer's abdomen, and optionally a receiving member or bag is attached to the body side ostomy member for receiving exudates from the ostomy in case of a two-piece appliance. The body side member comprises an adhesive wafer for securing the device to the wearer's abdomen, said wafer
- 25 having a hole for accomodating the ostomy and conveying the material discharged through the artificial orifice or opening into the collection bag.

Wafers and ostomy devices are manufactured in a variety of different standard shapes, sizes and configurations to meet the many different needs of the users. Although these standard products meet the needs of the average user, they do

not ideally meet the needs of any particular individual. In most cases, the user must adapt the product prior to use to suit his or her anatomy or lifestyle. Typical modifications which can be performed include cutting of the stoma receiving opening in the wafer, trimming the outside of the wafer, addition of convex
5 inserts, application of paste and filters and folding or trimming the pouch.

However, even these modifications may not result in an ideal product for the particular individual. Users may have difficulty in performing the modifications, as well. This may be due to poor dexterity, poor eyesight or diminished mental capacity. Some desired modifications may be very difficult or impossible without
10 special equipment. Some users may see making such modifications as taking too much time or for other reasons to be an undesirable task.

Thus, because of difficulties or simple reluctance on the part of the user, the modifications to the products are done poorly and as a result, product performance may suffer.

15 European patent publication No. EP 800 804 discloses the fabrication of customised ostomy devices according to which the ostomy devices are produced having attributes selected according to measurement information obtained from the respective patient.

This solution, however, involves substantial logistic problems with respect to
20 producing, storing and distributing the customised products.

It is the general object of this invention to eliminate the above problems by fabricating ostomy devices which are customised so as to be uniquely suited to the needs and preferences of each individual user. This object may be achieved in a variety of different ways, using technologies of different sophistication and cost.

25 BRIEF DESCRIPTION OF THE INVENTION

The present invention relates to a method for making a customised ostomy appliance including an adhesive wafer comprising the steps: measuring the outer contour/periphery of the stoma of the patient, recording the information relating

to the measurements of the stoma area, transforming the recorded information into electronic form, utilising the electronic information to select physical attributes of the ostomy device and have physical attributes selected in accordance with the measurement information transferred to the ostomy appliance.

- 5 Further, the invention relates to a method for making a customised ostomy appliance including an adhesive wafer and a collection bag comprising the steps: measuring the outer contour of the stoma of the patient, recording the information relating to the measurements of the stoma area, transforming the recorded information into electronic form, utilising the electronic information to select
- 10 physical attributes of the ostomy device and have physical attributes selected in accordance with the measurement information transferred to the ostomy appliance.

- Furthermore, the invention relates to a release liner having a customised printed cutting guide pattern corresponding to the outer contour of the stoma of a
- 15 patient.

Still further, the invention relates to a label having an adhesive for adhering to the release liner of an ostomy appliance, said label comprising a customised printed cutting guide pattern corresponding to the stomal area of a patient.

- Yet further, the invention relates to a customised ostomy appliance including an
- 20 adhesive wafer having a stoma receiving opening, attachment means for attaching an ostomy collection bag and a customised printed pattern indicating a cutting line for adapting the appliance to the specific ostomate.

- Furthermore, the invention relates to a customised ostomy appliance including an adhesive wafer having a stoma receiving opening and an ostomy collection
- 25 bag and a customised printed pattern indicating the a cutting line for adapting the appliance to the specific ostomate.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a method for making a customised ostomy appliance including an adhesive wafer comprising the steps: measuring the outer contour of the stoma of the patient, recording the information relating to the
5 measurements of the stoma area, transforming the recorded information into electronic form, utilising the electronic information to select physical attributes of the ostomy device and have physical attributes selected in accordance with the measurement information transferred to the ostomy appliance, wherein the information is utilised for printing a cutting guide pattern on a material for adhering to
10 the adhesive wafer. The method offers a simple and efficient method of customising ostomy appliances without involving substantial logistic problems with respect to producing, storing and distributing the customised products.

The information is preferably stored in electronic form together with information identifying the patient in a manner known per se and then be used for controlling
15 the printing of a customised cutting guide or pattern for the patient.

The printing may be carried out in-line by printing directly on the material on finished ostomy appliance as a last step or in an earlier separate step.

In use, the printed cutting guide is placed on the adhesive wafer or the release liner and the hole of the wafer is adapted to the periphery of the stoma of the
20 specific patient. Such cutting may be performed by the patient or by the person being in charge of delivering the ostomy appliances to the patient, typically a nurse or other assistant persons, e.g. in the patient's home, in a clinic or in a hospital. It is also foreseen that the cutting may be performed by a manufacturer or distributor who is then able to deliver customised products directly to the users
25 by mail.

Another embodiment of the invention relates to a method for making a customised ostomy appliance including an adhesive wafer and a collection bag comprising the steps: measuring the outer contour of the stoma of the patient, recording the information relating to the measurements of the stoma area, transforming the
30 recorded information into electronic form, utilising the electronic information to

select physical attributes of the ostomy device and have physical attributes selected in accordance with the measurement information transferred to the ostomy appliance, wherein the information is utilised for printing a cutting guide pattern on a material for adhering to the adhesive wafer.

- 5 In one embodiment of the invention the pattern is printed on a release liner for placing on the adhesive wafer which enables simple production of series of customised ostomy appliances.

In another preferred embodiment the pattern is printed on a material having an adhesive backing for placing on the release liner which enables a customising of
10 the ostomy appliance just before delivery which is cost saving with respect to transportation and storing of customised ostomy appliances. The pattern typically delivered in the form of a number of adhesive labels enabling an easy and simple customisation of a standard product.

In a further aspect, the invention relates to a release liner having a customised
15 printed cutting guide pattern corresponding to the stomal area of a patient. The pattern defining the cutting line may obtained by recording the information relating to the measurements of the stoma area of the patient, transforming the recorded information into electronic form, optionally storing the data and utilising the electronic information to select physical attributes of the ostomy device and
20 have physical attributes selected in accordance with the measurement information transferred to the release liner utilising the information for printing the cutting guide pattern on a material for covering to the adhesive wafer.

In a still further and preferred aspect the invention relates to a label having an adhesive for adhering to the release liner of an ostomy appliance having a stoma
25 receiving opening, said label comprising a customised printed cutting guide pattern corresponding to the stomal area of a patient. The customised pattern defining the cutting line may be obtained by recording the information relating to the measurements of the stoma area of the patient, transforming the recorded information into electronic form, optionally storing the data and utilising the
30 electronic information to select physical attributes of the ostomy device and have

physical attributes selected in accordance with the measurement information transferred to an adhesive label utilising the information for printing the pattern on a material having an adhesive backing.

The invention furthermore relates to a customised ostomy appliance including an
5 adhesive wafer having a stoma receiving opening, attachment means for attaching an ostomy collection bag and a customised printed pattern indicating the cutting line for adapting the appliance to the specific ostomate. The customised pattern defining the cutting line is defined after measuring the outer contour of the stoma of the patient, recording the information relating to the measurements
10 of the stoma area, transforming the recorded information into electronic form, optionally storing the data and utilising the electronic information to select physical attributes of the ostomy device and have physical attributes selected in accordance with the measurement information transferred to the ostomy appliance wherein it has been utilised for printing the pattern on a material for covering the
15 adhesive wafer.

In a still further embodiment, the invention relates to a customised ostomy appliance including an adhesive wafer having a stoma receiving opening and an ostomy collection bag and a customised printed pattern indicating the cutting line for adapting the appliance to the specific ostomate. The cutting line is defined by
20 measuring the outer contour of the stoma of the patient, recording the information relating to the measurements of the stoma area, transforming the recorded information into electronic form, optionally storing the data and utilising the electronic information to select physical attributes of the ostomy device and have physical attributes selected in accordance with the measurement information
25 transferred to the ostomy appliance wherein it has been utilised for printing the pattern on a material for covering the adhesive wafer.

The adhesive wafer of an ostomy appliance may be made from any appropriate skin friendly material known per se for the purpose and may also comprise a top film known per se. The skin-friendly adhesive may be any skin-friendly adhesive
30 known per se, e.g. an adhesive comprising hydrocolloids or other moisture absorbing constituents for prolonging the time of use. The adhesive may suitably

be of the type disclosed in those disclosed in GB patent specifications Nos. 1 280 631 and 1,586,182, in EP published applications Nos. 0 097 846, 0 264 299, 0 272 149 and 0 415 183, , in WO publication No. 88/06894, and in US patent specification No. 3,419,006, 3,972,328, 4,538,603 and 4,867,748. Especially
5 preferred are the adhesives disclosed in US patents Nos. 4,367,732, 5,051,259 and 5,714,225.

The attachment means for attaching an ostomy collection bag may be a system known per se comprising matching coupling rings or matching flanges and adhesive surfaces.

- 10 A release liner may for instance be siliconized paper. It does not need to have the same contour as the dressing, e.g. a number of dressings may be attached to a larger sheet of protective cover. The protective cover is not present during the use of the dressing of the invention and is therefore not an essential part of the invention.
- 15 A label may be prepared from any appropriate material which may be provided with a suitable adhesive for adhering the label to the release liner and hold it in place when cutting along the cutting guide as long as the materials are compatible and the adhesive has no adverse effect on the ostomy appliance.

The printing of the cutting line may carried out using any suitable manner known
20 per se for printing on the material in question.

A collection bag may be any suitable conventional collection bag known per se.

CLAIMS

1. A method for making a customised ostomy appliance including an adhesive wafer comprising the steps: measuring outer contour of the stoma of the patient, recording the information relating to the measurements of the stoma area, trans-
5 forming the recorded information into electronic form, utilising the electronic information to select physical attributes of the ostomy device and have physical attributes selected in accordance with the measurement information transferred to the ostomy appliance, characterised in that the information is utilised for printing a cutting guide pattern on a material for adhering to the adhesive wafer.
- 10 2. A method for making a customised ostomy appliance including an adhesive wafer and a collection bag comprising the steps: measuring the outer periphery of the stoma of the patient, recording the information relating to the measurements of the stoma area, transforming the recorded information into electronic form, utilising the electronic information to select physical attributes of the
15 ostomy device and have physical attributes selected in accordance with the measurement information transferred to the ostomy appliance, characterised in that the information is utilised for printing a cutting guide pattern on a material for adhering to the adhesive wafer.
3. A method as claimed in claim 1 or 2, characterised in that the pattern is
20 printed on a release liner for placing on the adhesive wafer.
4. A method as claimed in claim 1 or 2, characterised in that the pattern is printed on a material having an adhesive backing for placing on the release liner.
5. A release liner having a customised printed cutting guide pattern corresponding to the stomal area of a patient obtained by recording the information relating
25 to the measurements of the stoma area of the patient.
6. A label having an adhesive backing for adhering to the release liner of an ostomy appliance having a stoma receiving opening, said label comprising a

customised printed cutting guide pattern indicating the a cutting line for adapting the opening to the specific ostomate.

7. A customised ostomy appliance including an adhesive wafer having a stoma receiving opening, attachment means for attaching an ostomy collection bag and
- 5 a customised printed pattern indicating a cutting line for adapting the opening to the specific ostomate.
8. A customised ostomy appliance including an adhesive wafer having a stoma receiving opening and an ostomy collection bag and a customised printed pattern indicating a cutting line for adapting the receiving opening to the specific
- 10 ostomate.

INTERNATIONAL SEARCH REPORT

International application No. —

PCT/DK 99/00593

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61F 5/445

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9817212 A1 (COLOPLAST A/S), 30 April 1998 (30.04.98), page 16, line 16 - line 26, figures 15-16	5-8
A	—	1-4
A	EP 0800804 A1 (BRISTOL-MYERS COMPANY), 15 October 1997 (15.10.97), figure 1, abstract	1-4
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☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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INTERNATIONAL SEARCH REPORT
Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9817212 A1	30/04/98	AU 4616397 A	15/05/98
		DK 116696 A	23/04/98
		NO 991905 A	22/06/99
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